

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
6 February 2003 (06.02.2003)

PCT

(10) International Publication Number  
**WO 03/009773 A2**

(51) International Patent Classification<sup>7</sup>:

**A61F**

MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(21) International Application Number: PCT/US02/22098

(22) International Filing Date: 5 July 2002 (05.07.2002)

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/308,071 26 July 2001 (26.07.2001) US

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

(74) Agent: ALEXANDER, Tony, D.; Technology Legal Counsel LLC, P.O. Box 1728, Evans, GA 30809 (US).

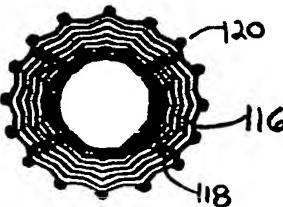
Published:

- without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,

(54) Title: REMOVABLE STENT AND METHOD OF USING THE SAME



(57) Abstract: The present invention, in an exemplary embodiment, provides a stent, which combines many of the excellent characteristics of both silicone and metal stents while eliminating the undesirable ones. In particular, it is an objective of a preferred embodiment of the present invention to provide a stent that is easily installed, yet removable. Moreover, the stent does not cause material infections and has the capacity to reduce infection. Therefore, a principal objective of a preferred embodiment in accordance with the present invention is to provide a prosthesis that is suitable for both permanent and temporary use while being easy to insert, reposition and remove. This prosthesis is also suitable for targeted delivery of antimicrobial and chemotherapeutic agents.

Additionally, a principal objective in accordance with the present invention is to provide a family of stents where the relative hardness/softness of regions of the stent can differ from other regions of the stent to provide additional patient comfort and resistance to radial forces. An exemplary embodiment also provides a family of stents with novel interstice configurations that facilitate flexibility, durability and/or proper installation.

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## REMOVABLE STENT AND METHOD OF USING THE SAME

### FIELD OF THE INVENTION

The present invention relates generally to medical devices directed to the prevention of nonvascular vessel or passageway 5 occlusion, and more particularly to removable tracheal/bronchial stents and methods for utilizing these stents in the treatment of both benign and malignant conditions.

### BACKGROUND OF THE INVENTION

Stents are devices that are inserted into a vessel or passage to 10 keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, stents are commonly used to keep blood vessels open in the coronary arteries and they are frequently inserted into the ureters to maintain drainage from the kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma or 15 the esophagus for strictures or cancer.

In particular, airway stents are principally utilized for four indications, namely: (1) re-establishment of airway patency due to extrinsic tracheobronchial compression from either mass or lymph nodes; (2) re-establishment of airway patency due to intrinsic tracheobronchial 20 obstruction from malignant or benign disease; (3) to cover a fistula track secondary to tracheo-esophageal fistula; and/or (4) to maintain airway patency in patients with tracheobronchial malacia. There are currently two basic types of stents available for some but not all of these indications: polymer or metal.

In 1990 a silicone stent developed by Dumon was reported upon in the medical literature, it is currently the most widely utilized stent in the world. The primary advantage of the silicone stent is its removability. However, this stent must be placed through a rigid metal tube (rigid 5 bronchoscopy), in an operating suite, under general anesthesia, which increases the cost of the procedure and potentially places the patient at greater risk for complications. This technique requires extensive training and is only performed at specialized centers. The Dumon stent is thick-walled, which increases airway resistance and decreases 10 mucociliary clearance. This problem leads to mucous impaction and tracheobronchitis. Additionally, these polymer stents are of fixed luminal diameter and do not self expand to meet the changing contour of the airway. This leads to a problem with stent migration. The cylindrical tube 15 design does not conform to curved or conical airway anatomy and they also cause the formation of granulation tissue, which results from airway irritation.

In light of these disadvantages, and at the expense of removability, industry has moved away from the polymer stent in favor of the self-expanding metal stent. The two most widely used are the 20 ultraflex and wall stent, which have shape memory characteristics. They are self-expanding and can be placed through a flexible bronchoscope, under conscious sedation, using local anesthesia in an outpatient setting. They have sufficient wall to lumen ratio, minimal interference with mucociliary clearance and conform to difficult airway anatomy. 25 Unfortunately, after approximately six weeks, the wire mesh in these

stents becomes epithelialized, thus making removal difficult, if not impossible.

Rejection of the stent can occur with severe airway irritation and tracheobronchitis that is impossible to treat because the nidus for the 5 infection is the metal, which cannot be removed. Because of the inability to remove these stents, they are indicated only as a last resort for benign disease. Additionally, these stents can be challenging to deploy because they can elongate or foreshorten, depending upon the diameter of the airway.

10 An additional disadvantage of conventional metal stents is that they can migrate, like polymer stents, since the axial working length of these stents varies when the stent is radially compressed. Attempts have been made to address this problem by providing a stent that is comprised of knit layers of metal to form a wire mesh with peristaltic 15 capabilities. Unfortunately, by preparing a stent from twisted wire portions, the likelihood of tissue aggravation increases because the weaved loops of the stent dislocate when subjected to radial compression. Moreover, for certain stents, sharp edges exist at the final loop ends.

20 As a result, physicians have the intractable dilemma of having to decide whether the patient should undergo the intricate procedure to receive the removable polymer stent, which can migrate and/or cause granulation tissue formation, and is subject to recurrent infections. Though the metal stent is easier to implant, the risk of infection and 25 granulation tissue formation is not reduced because the stents become epithelialized and, therefore, impossible to remove.

An additional limitation of conventional stents is the inability to adapt a single design to diverse locations of the patient's anatomy. For example, as a result of differences in topology, physicians are generally required to find different devices from different manufacturers to

5 address conditions in varying parts of the patient's anatomy. A uniform design and method of implantation while still allowing for the shape and resiliency modification necessary to accommodate the intricacies of various lumens throughout the body would be advantageous. Therefore,

10 there is a need for a uniform prosthesis or family of related devices that can address various anatomical challenges while allowing the physician to develop a comfort level with a particular product design and implantation method.

Therefore, there also remains an existing need for a prosthesis that is; removable, prevents epithelialization thereof, does not migrate, and is

15 suitably configured to minimize infections and airway irritation. This is of principal importance because in tracheobronchial stenting, unlike other lumens in the body, the airway is constantly exposed to inhaled bacteria thus increasing the risk of infection. However, there is a need for a prosthesis that carries the above advantages while being suitable for

20 use in a wide variety of anatomic locations within a patient. The configuration must also facilitate a method of introduction that prevents the premature elongation and foreshortening of the stent while suitably engaging the desired implantation location. The stent must also retain its axial length while undergoing radial compression. Moreover, there is

25 an existing need for a stent that has both antimicrobial and

chemotherapeutic properties so that the stent can be indicated as an early stage therapy.

There is an existing need for a prosthesis that is designed to accommodate varying tissue types in lumens of the body. In particular,

5 there is a need for a family of stents where the relative hardness/softness of regions of the stent can differ from other regions of the stent to provide additional patient comfort and resistance to radial forces. There is also an existing need for a family of stents with novel interstice configurations that facilitate flexibility, durability and/or proper

10 installation. Presently, there is a need for a self-expanding stent have the above benefits that also defines a plurality of apertures at the termini of the stent for, *inter alia*, removal of the stent.

### **SUMMARY OF EXEMPLARY EMBODIMENTS**

It is a principal purpose of the present invention to provide a stent,

15 in accordance with an exemplary embodiment of the present invention, which combines many of the excellent characteristics of both silicone and metal stents while eliminating the undesirable ones. In particular, it is an objective of a preferred embodiment in accordance with the present invention to provide a stent that is easily installed, yet

20 removable. Moreover the stent in accordance with this embodiment of the present invention would not cause material infections and may be capable of reducing infection. Therefore, a principal objective of a preferred embodiment in accordance with the present invention is to provide a prosthesis that is suitable for both permanent and temporary

25 use while being easy to insert, reposition and remove.

Another principal objective in accordance with a preferred embodiment of the present invention is to provide a tracheal/bronchial stent that is a hybrid of the metal and elastic stents, which offers optimal characteristics for the management of diseased airways. In the 5 furtherance of this and other objectives, a stent is provided that has a shape-memory frame that is sufficiently covered with a thin coating so as to prevent epithelialization.

An additional objective of an exemplary device in accordance with the present invention is to provide a prosthesis that is suitable for 10 use in other anatomical locations within a patient such as, by way of example only and not to be construed as limiting, the colon, the biliary tract, the urinary tract, etc., without departing from the basic product design and method manufacture and implantation contemplated by the present invention.

15 A principal objective of a preferred embodiment of the present invention is to provide a stent that may be stamped from preferably a single material that is capable of maintaining its axial working length when radially compressed. To this end, the stent does not have a seam that could aggravate luminal tissue.

20 It is yet another objective of an exemplary embodiment of the present invention to provide a stent that can be indicated for the treatment of benign and malignant disease and improve the way clinicians treat malignant airway obstruction.

25 Still another objective of the present invention is to provide a stent and method for installing the stent that is economical and suitable for routine purposes. In the furtherance of this and other objectives, the

stent will be self-expanding and have the ability to be placed through a flexible bronchoscope under local anesthesia in the outpatient setting. Moreover, the stent will have minimal migration, cause minimal tissue granulation, will not foreshorten after deployment and mucociliary 5 clearance will not be problematic.

Yet another objective of an exemplary embodiment in accordance with the present invention is to provide a prosthesis that will have superior internal to external diameter ratio, superior radial force with dynamic expansion, while being suitable for use in pediatric and 10 adult patients with malignant and benign disease.

An additional objective in accordance with an exemplary embodiment of the present invention is to provide a removable self-expanding stent, formed of shape-memory material, which has the ability to be integrated with an antimicrobial agent thus dramatically reducing 15 the incidence of infection. In the furtherance of this and other objectives, the antimicrobial agent can be coupled with the shape-memory material and/or the polymeric anti-epithelializing material that is associated with the shape-memory material.

Another objective in accordance with a preferred embodiment of 20 the present invention is to provide a method of use, method of manufacture and a stent appropriately configured to serve as a targeted delivery device for chemotherapeutic agents so as to deliver the chemotherapeutic agent to sites of choice so as to provide the chemotherapeutic activity, prevent occlusion or both.

25 A principal objective of an exemplary stent in accordance with the present invention is to provide a family of stents where the relative

hardness/softness of regions of the stent can differ from other regions of the stent to provide additional patient comfort and resistance to radial forces.

An additional objective in accordance with an exemplary embodiment is to provide a family of stents with novel interstice configurations that facilitate flexibility, durability and/or proper installation.

Still another objective of a preferred embodiment of the present invention is to provide a self-expanding stent have the above benefits that also defines a plurality of apertures at the termini of the stent for, *inter alia*, removal of the stent.

Yet another objective in accordance with an exemplary embodiment is to provide a coated stent. In the furtherance of this and other objectives, an exemplary coated stent has a coating that is preferably anchored with the stent about the proximal and distal ends and is free floating there between. Moreover, the coating allows for full and independent self-expansion even after being constrained and sterilized on the delivery system. It is an additional characteristic of this objective to provide a coating that does not have to be porous but must be sufficiently durable to remain functional when the stent is flexed, recaptured or deployed.

An additional objective in accordance with a preferred embodiment of the present invention is to provide an uncovered stent that is easily removable and prevents epithelialization. In the furtherance of this and other objectives, the stent is preferably electropolished.

Further objectives, features and advantages of the invention will be apparent from the following detailed description taken in conjunction with the accompanying drawings.

#### **BRIEF DESCRIPTION OF THE FIGURES**

5 FIG. 1 shows an elevated side perspective view of an exemplary luminal stent in accordance with the present invention.

FIG. 2 shows a side perspective view of the luminal stent shown in FIG. 1.

10 FIG. 3 shows an aerial perspective view of interior of the luminal stent shown in FIG. 1.

FIG. 4 shows an elevated side perspective view alternative embodiment of a luminal stent in accordance with the present invention.

15 FIG. 5 shows a side perspective view of an alternative embodiment of an exemplary luminal stent in accordance with the present invention.

FIG. 6 shows an elevated perspective view of an alternative embodiment of an exemplary luminal stent in accordance with the present invention.

20 FIG. 7 shows an aerial perspective view through the interior of the luminal stent shown in FIG. 6.

FIG. 8 shows a side perspective view of the luminal stent shown in FIG. 6.

25 FIG. 9 shows a perspective view showing the longitudinal expanse of the D-shaped configuration of a tracheal appliance in accordance with the present invention.

FIG. 10 shows an end view of an exemplary D-shaped tracheal appliance, in accordance with the present invention, showing the external shape of the appliance.

FIG. 11 shows an end view of an exemplary D-shaped tracheal 5 appliance, in accordance with the present invention, looking down the lumen between the distal and proximal ends thereof.

FIG. 12 shows an aerial perspective view of the top surface of the D-shaped tracheal appliance shown in FIG. 9.

FIG. 13 shows a side perspective view of an exemplary 10 embodiment of a medical appliance, in accordance with the invention shown in FIG. 9, wherein the D-shaped appliance is resting on its substantially flat surface.

FIG. 14 shows a magnified view of the scaffolding and interstice topology of the medical appliance shown in FIG. 1.

15 FIG. 15 shows a magnified portion of the scaffolding and interstice topology of the medical appliance of FIG. 1, showing how modifications in geometric dimensions affect functionality.

FIG. 16 shows an elevated side perspective view of an exemplary Y-stent luminal stent in accordance with the present invention.

20

#### DETAILED DESCRIPTION OF AN EMBODIMENT

A preferred embodiment of the stent, in accordance with the present invention, provides a removable stent that prevents epithelialization of the stent and is suitably configured to minimize infections and airway irritation. The exemplary stent is not subject to 25 premature elongation and foreshortening but is capable of engaging the desire implantation location. The stent also retains its axial length while

undergoing radial compression. Additionally, the stent has both antimicrobial and/or chemotherapeutic properties so that the stent can be indicated as an early stage therapy.

The term "antimicrobial agent" as used in the present invention 5 means antibiotics, antiseptics, disinfectants and other synthetic moieties, and combinations thereof, that are soluble in organic solvents such as alcohols, ketones, ethers, aldehydes, acetonitrile, acetic acid, formic acid, methylene chloride and chloroform. Classes of antibiotics that can possibly be used include tetracyclines (i.e. minocycline), 10 rifamycins (i.e. rifampin), macrolides (i.e. erythromycin), penicillins (i.e. naftillin), cephalosporins (i.e. cefazolin), other beta-lactam antibiotics (i.e. imipenem, aztreonam), aminoglycosides (i.e. gentamicin), chloramphenicol, sulfonamides (i.e. sulfamethoxazole), glycopeptides (i.e. vancomycin), quinolones (i.e. ciprofloxacin), fusidic acid, 15 trimethoprim, metronidazole, clindamycin, mupirocin, polyenes (i.e. amphotericin B), azoles (i.e. fluconazole) and beta-lactam inhibitors (i.e. sulbactam).

Examples of specific antibiotics that can be used include minocycline, rifampin, erythromycin, naftillin, cefazolin, imipenem, 20 aztreonam, gentamicin, sulfamethoxazole, vancomycin, ciprofloxacin, trimethoprim, metronidazole, clindamycin, teicoplanin, mupirocin, azithromycin, clarithromycin, ofloxacin, lomefloxacin, norfloxacin, nalidixic acid, sparfloxacin, pefloxacin, amifloxacin, enoxacin, fleroxacin, temafloxacin, tosufloxacin, clinafloxacin, sulbactam, clavulanic acid, 25 amphotericin B, fluconazole, itraconazole, ketoconazole, and nystatin. Other examples of antibiotics, such as those listed in U.S. Pat. No.

4,642,104, herein incorporated by reference, will readily suggest themselves to those of ordinary skill in the art.

Examples of antiseptics and disinfectants are thymol,  $\alpha$ -terpineol, methylisothiazolone, cetylpyridinium, chloroxylenol, hexachlorophene, 5 cationic biguanides (i.e. chlorhexidine, cyclohexidine), methylene chloride, iodine and iodophores (i.e. povidone-iodine), triclosan, furan medical preparations (i.e. nitrofurantoin, nitrofurazone), methenamine, aldehydes (glutaraldehyde, formaldehyde) and alcohols. Other examples of antiseptics and disinfectants will readily suggest themselves to those 10 of ordinary skill in the art.

It must also be kept in mind that, though not equivalent, a stent in accordance with the present invention may be prepared with antimicrobial agents in other ways customary in the art. For example, the stent may be made in its entirety or in part of an antimicrobial metal, or 15 at least one surface of the stent may have embedded, by ion beam assisted deposition, therein with atoms of an antimicrobial metal. Other suitable examples can be found in the art, for example U.S. Pat. No. 5,520,664, which is incorporated herein by reference. Moreover, chemotherapeutic agents can be coupled with an exemplary stent of 20 the present invention in a manner analogous to that of antimicrobial agents.

Exemplary chemotherapeutic agents include but are not limited to cis-platinum, paclitaxol, 5-flourouracil, gemcytobine and navelbine. The chemotherapeutic agents are generally grouped as DNA-interactive 25 Agents, Antimetabolites, Tubulin-Interactive Agents, Hormonal agents and others such as Asparaginase or Hydroxyurea. Each of the groups of

chemotherapeutic agents can be further divided by type of activity or compound. The chemotherapeutic agents used in combination with the anti-cancer agents or benzimidazoles of this invention include members of all of these groups. For a detailed discussion of the chemotherapeutic 5 agents and their method of administration, see *Dorr, et al, Cancer Chemotherapy Handbook, 2d edition, pages 15-34, Appleton & Lange (Connecticut, 1994)* herein incorporated by this reference.

DNA-Interactive Agents include the alkylating agents, e.g. Cisplatin, Cyclophosphamide, Altretamine; the DNA strand-breakage 10 agents, such as Bleomycin; the intercalating topoisomerase II inhibitors, e.g., Dactinomycin and Doxorubicin); the nonintercalating topoisomerase II inhibitors such as, Etoposide and Teniposide; and the DNA minor groove binder Plicamycin. The alkylating agents form covalent chemical adducts with cellular DNA, RNA, and protein 15 molecules and with smaller amino acids, glutathione and similar chemicals. Generally, these alkylating agents react with a nucleophilic atom in a cellular constituent, such as an amino, carboxyl, phosphate, or sulfhydryl group in nucleic acids, proteins, amino acids, or glutathione. The mechanism and the role of these alkylating agents in cancer therapy 20 are not well understood. Typical alkylating agents include: Nitrogen mustards, such as Chlorambucil, Cyclophosphamide, Isofamide, Mechlorethamine, Melphalan, Uracil mustard; aziridines such as Thiotepa; methanesulfonate esters such as Busulfan; nitroso ureas, such as Cannustine, Lomustine, Streptozocin; platinum complexes, such as 25 Cisplatin, Carboplatin; bioreductive alkylator, such as Mitomycin, and Procarbazine, Dacarbazine and Altretamine; DNA strand breaking agents

include Bleomycin; DNA topoisomerase II inhibitors include the following: Intercalators, such as Amsacrine, Dactinomycin, Daunorubicin, Doxorubicin, Idarubicin, and Mitoxantrone; nonintercalators, such as Etoposide and Teniposide. The DNA minor groove binder is Plicamycin.

5        The Antimetabolites interfere with the production of nucleic acids by one or the other of two major mechanisms. Some of the drugs inhibit production of the deoxyribonucleoside triphosphates that are the immediate precursors for DNA synthesis, thus inhibiting DNA replication. Some of the compounds are sufficiently like purines or pyrimidines to be

10      able to substitute for them in the anabolic nucleotide pathways. These analogs can then be substituted into the DNA and RNA instead of their normal counterparts. The Antimetabolites useful herein include: folate antagonists such as Methotrexate and trimetrexate pyrimidine antagonists, such as Fluorouracil, Fluorodeoxyuridine, CB3717,

15      Azacytidine, Cytarabine, and Flouxuridine purine antagonists include Mercaptopurine, 6-Thioguanine, Fludarabine, Pentostatin; sugar modified analogs include Cytarabine, Fludarabine; ribonucleotide reductase inhibitors include Hydroxyurea.

20      Tubulin Interactive agents act by binding to specific sites on Tubulin, a protein that polymerizes to form cellular microtubules. Microtubules are critical cell structure units. When the interactive agents bind on the protein, the cell cannot form microtubules. Tubulin Interactive agents include Vincristine and Vinblastine, both alkaloids and Paclitaxel.

25      Hormonal agents are also useful in the treatment of cancers and tumors. They are used in hormonally susceptible tumors and are usually

derived from natural sources. These include: estrogens, conjugated estrogens and Ethinyl Estradiol and Diethylstilbestrol, Chlorotrianisene and Idenestrol; progestins such as Hydroxyprogesterone caproate, Medroxyprogesterone, and Megestrol; androgens such as testosterone, 5 testosterone propionate; fluoxymesterone, methyltestosterone; Adrenal corticosteroids are derived from natural adrenal cortisol or hydrocortisone. They are used because of their anti-inflammatory benefits as well as the ability of some to inhibit mitotic divisions and to halt DNA synthesis. These compounds include Prednisone, 10 Dexamethasone, Methylprednisolone, and Prednisolone.

Leutinizing hormone releasing hormone agents or gonadotropin-releasing hormone antagonists are used primarily the treatment of prostate cancer. These include leuprolide acetate and goserelin acetate. They prevent the biosynthesis of steroids in the testes.

15 Antihormonal antigens include antiestrogenic agents such as Tamoxifen, antiandrogen agents such as Flutamide; and antiadrenal agents such as Mitotane and Aminoglutethimide. Hydroxyurea appears to act primarily through inhibition of the enzyme ribonucleotide reductase. Asparaginase is an enzyme that converts asparagine to 20 nonfunctional aspartic acid and thus blocks protein synthesis in the tumor.

While the foregoing represents some preferred embodiments of the present invention, other antimicrobial and chemotherapeutic agents and coating techniques may be utilized.

25 A preferred embodiment of a stent of the present invention is made of a shape-memory material such as nickel titanium (nitinol). A

tracheal stent, in accordance with the present invention, has a substantially D shaped scaffolding to accommodate the trachea, which has stiff cartilaginous C rings that form the anterior and side walls of this organ while the posterior wall is elastic. The shape-memory material 5 frame may be stamped into a variety of patterns such as that disclosed in German Pat. No. DE-199-06-956, herein incorporated in its entirety by reference.

The frame may be coated with a thin coating (preferably silicone, polyurethane or comparable material adaptable by one skilled in the 10 art) to the extent sufficient to prevent the stent from becoming epithelialized and facilitating removal. In a preferred embodiment, the coating is coupled with the stent about the proximal and/or distal ends and is not anchored to the stent there between. The coating may be porous, but is not required to be. Rather it is preferable that the coating 15 be sufficiently durable to remain functional when the stent is flexed, recaptured or deployed. Moreover, the material from which the coating is selected is limited only by the requirement that the coating allow for full and independent self-expansion even after being constrained and sterilized on the delivery system. It must also be noted that the stent may 20 alternatively be polished. The polishing step facilitates removal of the stent and helps to prevent epithelialization. As a result the polished stent may be used with or without the above referenced coating. The polishing process comprises an electrical polishing process that produces a polished stent wall thickness to a range of about 175  $\mu\text{m}$  - 220 25  $\mu\text{m}$ , and preferably 205  $\mu\text{m}$ , which is about 40% thinner and reduces radial force by 50% with respect to conventional stents. Additionally, the

present polishing process provides for a proportional decrease of radial force radial force as wall thickness decreases.

The ends of the stent may be configured to have flanges to prevent migration. In an embodiment having flanges, the ends of each 5 flange are tapered slightly back into the airway thus preventing the ends of the stent from irritating the airway wall. However, providing a stent that is capable of retaining its axial working length while undergoing radial compression also prevents migration. As a result, the stent is more flexible and comfortable since the diameter of the stent can be 10 increased without shortening the stent. Moreover, the resiliency of the stent can be varied over the length and/or cross-section of the stent. Moreover, suture holes are provided so that suture may be used as an anchor to facilitate removal of the stent. To this end, the stent may be deployed with or without suture already coupled with the stent.

15 An exemplary bronchial stent, in accordance with the present invention, will have similar features as the tracheal stent except that it is substantially tubular in shape. Though the stents are not equivalent, in view of the present disclosure, one of ordinary skill in the art would be able to make the necessary modifications to provide an exemplary 20 tracheal stent.

It should also be kept in mind that though the present discussion has principally focused on airway stents, the device and methods of the present invention are useful in a wide variety of locations within a patient, for example but not limited to the esophagus, trachea, colon, 25 biliary tract, urinary tract and vascular system. They are particularly advantageous for reliably delivering suitable therapeutic agents. In

fact, a stent in accordance with the present invention can be configured to serve as a chemotherapeutic and/or antimicrobial agent targeted delivery system suitable for use in a variety of other lumens throughout the anatomy of a patient.

5 An advantage of the manufacturing process for stents in accordance with the present invention is the ability to modify the relative hardness/softness of regions of the stent. In particular any given region of the stent can differ from other regions of the stent to provide additional patient comfort and resistance to radial forces. This is

10 preferably achieved by changing the relative geometries of the stent scaffolding interstices. In particular, by changing the height and/or width of the loop interstices, relative hardness/softness and radial strength can be adjusted. Moreover, the ability of the stent to flex and resist torsional strain can be enhanced by these interstice adjustments. It should be

15 noted that the present inventors have discovered that all of the above-enumerated features may be incorporated in a bronchial Y-stent. Moreover, unlike conventional Y-stents that are either rubber and/or comprise a modular configuration of parts, a Y-stent in accordance with the present invention is a unitary self-expanding memory metal

20 construction.

Turning now to the figures where like numerals refer to like components, of exemplary appliances in accordance with the present invention, the medical appliances are referred to generally with reference numerals 110, 210 and 310. Referring particularly to FIGS. 1-5, 25 a medical appliance 110, is provided that has a unitary memory metal construction. The appliance 110 itself, defines a lumen there through

which extends the longitudinal distance of the appliance 110 from the proximal end 112 to the distal end 114. The appliance 110 is preferably a luminal stent having a middle section 113 of a defined diameter that is dimensionally narrower than the defined diameter at the proximal end 5 112 and/or the distal end 114. FIG. 4 shows a luminal stent in accordance with the present invention that has a flared distal end 114 but not a flared proximal end 112. The appliance can be configured to have the opposite ends flared or no flared ends at all. The luminal stent also is formed of memory metal and preferably has unique geometrical 10 interstices 116 laser etched therein. However, other conventional ways of forming interstices in unitary stents, though not equivalent, are contemplated, may be employed and would be within the skill set of one in the art.

It cannot be overemphasized, however, that this does not mean 15 the knowledge that changes in the geometry of interstices 116 affect stent functionality is currently known in the art. To the contrary, the present inventors discovered the interrelation between interstice geometry, width, length and relative resistance to torsional stress and radial force. In fact, it can be said that the luminal stent 110 has 20 circumferential bands extending perpendicularly with respect to the luminal device's longitudinal axis. A connector 118 connects these bands to one another; the connector 118 is an additional means for adjusting stent functionality. In particular, the connector 118 defines a substantially U shaped member.

25 In a standard orientation, the substantially U-shape comprises preferably two leg members and a crossing member that connects with

and extends perpendicularly at a 90° angles with respect to the leg members. The present inventors discovered that if you modify the length of the crossing member and/or the leg members and/or the angle at which the crossing member and the leg members intersect, the relative 5 hardness/softness of the stent could be modified. The angles can be modified at varying acute angles short of 90°. The incremental changes correspondingly change certain characteristics of the stent. As a result, different regions of the luminal stent 110 can be given different rigidities to improve patient comfort and to facilitate luminal patency.

10 Moreover, various anatomical lumens may need different degrees of stent rigidity. As a result, stents in accordance with the present invention can be manufactured to exacting specifications to contour properly to various lumens in a patient's anatomy, which may need varying levels of structural support from the medical appliance.

15 Referring now to FIGS. 14 and 15, luminal stent 110 is shown having substantially U shaped connectors 118 having a crossing member 119a and at least two leg members 119b-c respectively. The present inventors discovered that if you increase/decrease the length of leg members 119b and/or 119c, increase/decrease the length of crossing 20 member 119a, and/or vary the angle at which crossing member 119a and leg members 119b-c intersect, you affect the functionality of the stent. In particular, the shorter the length of leg members 119a-b the less flexibility available in that portion of the stent. Taking particular note of FIG. 15, by way of example only, if you want to decrease the amount of 25 torsional flexibility of the luminal stent 110, you would have to modify the desired portion of the stent to resemble 118f. However, if you want a

stiffer appliance 110, you would have a configuration analogous to that of 118a.

In a preferred embodiment, the modification of interstice geometries and manipulation of the U shaped connection member to 5 achieve variable stent functionality is provided. The rigidity of the stent scaffolding or interstice matrix along with the torsionality of the stent itself is principally a function of these modifications. In an exemplary embodiment, the stents relative flexibility can be rated soft, medium or hard based on the degree of flex and torsionality. The less torsionality 10 and flex in the stent the harder the stent is rated.

An exemplary stent in accordance with the present invention with relatively great torsionality and radial flexibility would be rated soft. An exemplary soft rated stent comprises distance between U shaped connectors of about 4.5  $\mu\text{m}$  in the compressed state (i.e., contracted in 15 the 3mm tube subject to laser etching). Moreover, the length of the crossing member is preferably about 1.0  $\mu\text{m}$ . The lengths of the leg members are preferably about 1.5  $\mu\text{m}$  in length. Additionally the leg members may further comprise feet that attached to the remainder of the stent scaffolding. The feet can be adjusted from a standard length of 20 about 0.25  $\mu\text{m}$  to further adjust the characteristics of the stent. There is additionally a substantially rectangular member incorporated in the U shaped connector with similar capacity for variability. The variability factors and results of modifying the dimensions of the substantially rectangular members are similar to those evinced by leg length 25 dimensional modifications.

By way of example, but not to be construed in any way as limiting, the softness index or relative flexibility can be increase by increasing the various lengths discussed above. For example, by increasing the length of the legs and crossing members of the U shaped connector, flexibility 5 increases. However, with respect to the distance between U shaped members and distance between interstices in a preferred stent embodiment, there is an inverse correlation between length and softness. This relative softness/hardness indexing as a corollary of interstice dimensions is a novel aspect of preferred embodiment of the 10 present invention. As a practical rule of thumb, longer leg lengths coupled with acute angles provide for greater flexibility. Conversely, shorter leg lengths and more obtuse angles provide more rigidity. By way of non-limiting example, a U shaped connector with short legs deviating from the crossing member at angles greater than 90°, will be extremely 15 rigid and resistant to torsional strain as compared to a U shaped connector with longer legs diverging from the crossing member at angles less than 90°.

In addition to the length and spacing differences, the interstices themselves may define various shapes that by their very nature afford 20 novel functionality to the stent. The changes of functionality, however, are more a function of the dimensional differences of the various shapes rather than a function of the shapes themselves. Therefore, it is important to keep in mind that the dimensional differences discussed in the previous paragraph are determinative of the functionality accorded 25 the stent by the varying interstice geometries. It is for this reason that one of ordinary skill in the art, after being apprised of the present

invention, would be able to conceive of a number of interstice geometries to satisfy certain functionality criteria by keeping certain dimensional parameters constant.

Referring now to FIG. 16, an exemplary Y-shaped stent 410 is shown 5 that exemplifies the characteristics of luminal stents 110, 210 and 310. The Y-shaped stent also incorporates the advantages discussed above, including but not limited to, interstice geometrical advantages, polishing advantages, inward extending termini, suture apertures, antimicrobial and chemotherapeutic agent delivery, coating, etc.

10 In a preferred embodiment of a luminal stent in accordance with the present invention as shown in FIGS. 1-5, the proximal end 112 and the distal end 114 defines a plurality of apertures 120 for receiving suture. The luminal stent 110 may be deployed with or without suture engaged to facilitate the stent removal process.

15 As discussed above, a preferred luminal stent 110 further comprises a coating (not shown), which preferably extends substantially the entire distance of the luminal stent 110. In particular, in a preferred embodiment the luminal stent is coated from about the proximal end 112 to the distal end 114, inclusive of suture apertures 120.

20 Moreover, it is preferable that the coating is coupled with the luminal stent 110 about the proximal end 112 and distal end 114. The coating may be coupled to the luminal stent 110 by any number of adhesion systems available in the art. The principal requirement is that adhesive sufficiently couple the coating with luminal stent 110 so as to withstand 25 the pressures of stent deployment, expansion, flexing and removal.

As an alternative, and in other embodiments in addition to, the coating an exemplary luminal stent 110 is electropolished to remove rough edges and to create a thinner more resilient appliance. In particular, the electrical polishing process produces a polished luminal 5 stent wall thickness in the optimal range of about 175  $\mu\text{m}$  - 220  $\mu\text{m}$ , and preferably 205  $\mu\text{m}$ , which is about 40% thinner and reduces radial force by 50% with respect to conventional stents. Conventional stent polishing 10 methods comprise a fluid abrasive media extruded through an apparatus in abrading contact with inner and outer surfaces and circumferential openings of a stent. As a result, conventional stent polishing methods are incapable of polishing stents to an optimal thickness that allows the stent to demonstrate characteristics of a covered stent in accordance with the present invention, namely, epithelialization retardation, enhanced removability, etc. As shown in 15 Table 1, a polished stent in accordance with the present invention demonstrates desirable stent wall thickness, which is not achievable with shaping or staining processes. Moreover, standard polishing processing cannot achieve the desired stent wall thickness without compromising the integrity of the memory metal alloy and its shape memory 20 characteristics.

Table 1

Condition	Wall Thickness ( $\mu\text{m}$ )	$F_{\max}$ (Mean value)(mN)	Standard Deviation (mN)
Shaped	250	2733	296
Stained	233	1848	165
Polished	205	1518	53

The reduced radial force extends the useful life of the luminal stent 110 while also reducing significantly the pressure the stent exerts on the luminal tissue. It has been determined that as stent wall thickness decreases radial force decreases as well. The optimal range is an 5 important discovery since it allows for the design of a luminal stent 110 that achieves optimal stent migration prevention while exerting minimal pressure on the surrounding luminal tissue.

The radial strength of the stent is defined as the change of the diameter of the stent as a function of applied surrounding pressure once 10 the stent is deployed. The greater the radial strength of the stent, the more the appliance will resist deformation as a result of the forces imposed on the stent by the lumen. Radial strength of stents can generally be tested by conventional methods known in the art, such as DH Kim et al., *Korean J. Radiology*, June 2001; 2:75-79.

15 Luminal stents 210 and 310 in accordance with the present invention are shown in FIGS. 6-13 showing alternative interstice geometries. Not shown are a wide variety of interstice geometries that are also acceptable alternatives to the preferred, V, W, Z, S and X geometries claimed herein. Moreover, FIGS. 9-13 shows luminal stent 310 20 that has a substantially flat side 322 that extends longitudinally between proximal end 312 and distal end 314. As pointed out above, though stents 210 and 310 are shown with flared proximal ends 212 & 312 and distal ends 214 & 314, respectively, flared ends are not necessary. It should also be pointed out with respect to the respective ends of luminal 25 stents 110, 210 and 310; proximal 112, 212 & 312 and distal ends 114, 214 & 314 preferably orient inward towards its lumen. In particular, it is

preferable that suture apertures 120, 220 & 320 extend away from the lumen of the tissue of the patient and toward one another.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The 5 described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.

CLAIMS

What is claimed is:

1. 1. A medical appliance for placement within and removal from a portion of the anatomy of a patient, the appliance comprising:
  3. a scaffolding, the scaffolding configured to define a substantially cylindrical member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, such that when pressure is exerted along varying points of the longitudinal extension of the appliance, the appliance does not undesirably foreshorten or elongate.
1. 2. The medical appliance of claim 1, wherein along the longitudinal extension of the appliance, the scaffolding forms geometrical patterns.
1. 3. The medical appliance of claim 2, wherein the scaffolding further comprises a coating coupled with the scaffolding, the coating of sufficient thickness to prevent the medical appliance from becoming epithelialized when installed in the desired portion of the patient's anatomy.
1. 4. The medical appliance of claim 3, wherein the coating does not inhibit flexing or radial expansion of the medical appliance.
1. 5. The medical appliance of claim 4, wherein the coating is coupled with the medical appliance about the proximal and distal ends thereof.

1           6.    The medical appliance of claim 2, wherein the dimensions  
2    of the scaffolding geometry determine torsionality of the medical  
3    appliance.

1           7.    The medical appliance of claim 1, wherein the scaffolding  
2    is formed of a memory capable alloy.

1           8.    The medical appliance of claim 7, wherein the scaffolding  
2    is electropolished.

1           9.    The medical appliance of claim 1, wherein near the distal  
2    and proximal ends of the scaffolding the medical appliance further  
3    comprise a plurality of flanges that define apertures there through.

1           10.   The medical appliance of claim 2, further comprising a  
2    substantially U-shaped connector member coupled with portions of  
3    the geometrical patterns, the U-shaped connector comprising a  
4    crossing member and a plurality of leg members extending from the  
5    crossing member.

1           11.   The medical appliance of claim 10, wherein the  
2    substantially U-shaped connector further comprises a rectangular  
3    detent extending from a leg thereof.

1           12.   The medical appliance of claim 10, wherein the length of  
2    the leg members and the degree of the angle at which the legs  
3    extend from the crossing member determines the relative flexibility of  
4    the medical appliance.

1           13.   The medical appliance of claim 12, wherein the angle at  
2    which the leg members extend from the crossing member is greater  
3    than 90°.

1           14. The medical appliance of claim 13, wherein the medical  
2 appliance is relatively rigid.

1           15. The medical appliance of claim 13, wherein the angle at  
2 which the leg members extend from the crossing member is 90° or less.

1           16. The medical appliance of claim 14, wherein the medical  
2 appliance is relatively flexible.

1           17. The medical appliance of claim 2, wherein the  
2 geometrical patterns are substantially W-shaped.

1           18. The medical appliance of claim 2, wherein the  
2 geometrical patterns are substantially V-shaped.

1           19. The medical appliance of claim 2, wherein the  
2 geometrical patterns are substantially Z-shaped.

1           20. The medical appliance of claim 2, wherein the  
2 geometrical patterns are substantially S-shaped.

1           21. The medical appliance of claim 2, wherein the  
2 geometrical patterns are substantially X-shaped.

1           22. The medical appliance of claim 1, wherein the medical  
2 appliance is a stent for installation into the trachea of a patient.

1           23. The medical appliance of claim 22, wherein the  
2 scaffolding forms a D shaped lumen to accommodate comfortable  
3 tracheal installation and residence.

1           24. The medical appliance of claim 1, further comprising a  
2 second distal end wherein the scaffolding forms a substantially Y

3 shaped appliance comprising a primary lumen originating at the  
4 proximal end and diverging into two additional lumen terminating  
5 each at a respective distal end.

1 25. The medical appliance of claim 24, wherein the  
2 scaffolding is formed of a memory capable alloy.

1 26. The medical appliance of claim 24, wherein about the  
2 distal and proximal ends of the scaffolding the medical appliance  
3 further comprise a plurality of flanges that define apertures there  
4 through.

1 27. The medical appliance of claim 24, wherein along the  
2 longitudinal extension of the appliance, the scaffolding forms  
3 triangular patterns.

1 28. The medical appliance of claim 24, wherein the medical  
2 appliance is a stent for installation into the trachea, the scaffolding  
3 forms D shaped lumen to accommodate comfortable tracheal  
4 installation and residence.

1 29. The medical appliance of claim 1, wherein the memory  
2 capable alloy has antimicrobial properties.

1 30. The medical appliance of claim 29, wherein the  
2 antimicrobial alloy is selected from the group consisting of group  
3 eleven metals.

1 31. The medical appliance of claim 1, wherein the  
2 scaffolding further comprising an antimicrobial agent coupled  
3 therewith.

1       32. The medical appliance of claim 31, wherein the  
2 antimicrobial agent is selected from the group consisting of  
3 tetracyclines, rifamycins, macrolides, penicillins, cephalosporins,  $\beta$ -  
4 lactam antibiotics, aminoglycosides, chloramphenicols, sulfonamides,  
5 glycopeptides, quinolones, fusidic acid, trimethoprim, metronidazole,  
6 clindamycin, mupirocin, polyenes, azoles, and beta-lactam inhibitors.

1       33. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises an antiseptic or disinfectant coupled therewith.

1       34. The medical appliance of claim 33, wherein the antiseptic  
2 or disinfectant is selected from the group consisting of thymol,  $\alpha$ -  
3 terpineol, methylisothiazolone, cetylpyridinium, chloroxylenol,  
4 hexachlorophene, cationic biguanides, methylene chloride, iodine  
5 and iodophores, triclosan, furan medical preparations, methenamine,  
6 aldehydes and alcohols.

1       35. The medical appliance of claim 1, wherein the scaffolding  
2 may be made in its entirety or in part of an antimicrobial metal.

3       36. The medical appliance of claim 1, wherein at least one  
4 surface of the scaffolding may have embedded, by ion beam assisted  
5 deposition, therein with atoms of an antimicrobial metal.

1       37. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises a chemotherapeutic agent coupled therewith.

1       38. The medical appliance of claim 37, wherein the  
2 chemotherapeutic agent is selected from the group consisting of  
3 DNA-interactive Agents, Antimetabolites, Tubulin-Interactive Agents,  
4 Hormonal agents and others such as Asparaginase or Hydroxyurea.

1           39. The medical appliance of claim 37, wherein the DNA-  
2 Interactive Agents are selected from the group consisting of  
3 alkylating agents, the DNA strand-breakage agents, the intercalating  
4 topoisomerase II inhibitors, and the nonintercalating topoisomerase II  
5 inhibitors.

1           40. The medical appliance of claim 39, wherein the alkylating  
2 agents are selected from the group consisting of Nitrogen mustards,  
3 aziridines, nitroso ureas, platinum complexes, bioreductive alkylator,  
4 DNA strand breaking agents, Intercalators and nonintercalators.

1           41. The medical appliance of claim 38, wherein the  
2 Antimetabolites are selected from the group consisting of folate  
3 antagonists such as Methotrexate and trimetrexate; pyrimidine  
4 antagonists, such as Fluorouracil, Fluorodeoxyuridine, CB3717,  
5 Azacytidine, Cytarabine; Flouxuridine purine antagonists include  
6 Mercaptopurine, 6-Thioguanine, Fludarabine, Pentostatin; sugar  
7 modified analogs include Cyclophosphamide, Fludarabine; and ribonucleotide  
8 reductase inhibitors include Hydroxyurea.

1           42. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises a hormonal agent coupled therewith.

1           43. The medical appliance of claim 42, wherein the hormonal  
2 agent is selected from the group consisting of estrogens, conjugated  
3 estrogens; progestins; and androgens.

4           44. The medical appliance of claim 1, wherein the scaffolding  
5 further comprises an anti-hormonal agent coupled therewith.

1        45. The medical appliance of claim 44, wherein the anti-  
2 hormonal agent is selected from the group consisting of  
3 antiestrogenic, antiandrogen agents, and antiadrenal agents.

1        46. The medical appliance of claim 3, wherein the dimensions  
2 of the scaffolding geometry determine torsionality of the medical  
3 appliance.

1        47. The medical appliance of claim 3, wherein the scaffolding  
2 is formed of a memory capable alloy.

1        48. The medical appliance of claim 47, wherein the  
2 scaffolding is electropolished.

1        49. The medical appliance of claim 3, wherein near the distal  
2 and proximal ends of the scaffolding the medical appliance further  
3 comprise a plurality of flanges that define apertures there through.

1        50. The medical appliance of claim 3, further comprising a  
2 substantially U-shaped connector member coupled with portions of  
3 the geometrical patterns, the U-shaped connector comprising a  
4 crossing member and a plurality of leg members extending from the  
5 crossing member.

1        51. The medical appliance of claim 50, wherein the  
2 substantially U-shaped connector further comprises a rectangular  
3 detent extending from a leg thereof.

1        52. The medical appliance of claim 50, wherein the length of  
2 the leg members and the degree of the angle at which the legs  
3 extend from the crossing member determines the relative flexibility of  
4 the medical appliance.

1           53. The medical appliance of claim 52, wherein the angle at  
2 which the leg members extend from the crossing member is greater  
3 than 90°.

1           54. The medical appliance of claim 53, wherein the medical  
2 appliance is relatively rigid.

1           55. The medical appliance of claim 53, wherein the angle at  
2 which the leg members extend from the crossing member is 90° or less.

1           56. The medical appliance of claim 54, wherein the medical  
2 appliance is relatively flexible.

1           51. The medical appliance of claim 50, wherein the  
2 geometrical patterns are substantially W-shaped.

1           52. The medical appliance of claim 50, wherein the  
2 geometrical patterns are substantially V-shaped.

1           53. The medical appliance of claim 50, wherein the  
2 geometrical patterns are substantially Z-shaped.

1           54. The medical appliance of claim 50, wherein the  
2 geometrical patterns are substantially S-shaped.

1           55. The medical appliance of claim 50, wherein the  
2 geometrical patterns are substantially X-shaped.

1           56. The medical appliance of claim 3, wherein the medical  
2 appliance is a stent for installation into the trachea of a patient.

1        57. The medical appliance of claim 56, wherein the  
2 scaffolding forms a D shaped lumen to accommodate comfortable  
3 tracheal installation and residence.

1        58. The medical appliance of claim 1, further comprising a  
2 second distal end wherein the scaffolding forms a substantially Y  
3 shaped appliance having comprising a primary lumen originating at  
4 the proximal end and diverging into two additional lumen terminating  
5 each at a respective distal end.

1        59. The medical appliance of claim 58, wherein the  
2 scaffolding is formed of a memory capable alloy.

1        60. The medical appliance of claim 58, wherein near the  
2 distal and proximal ends of the scaffolding the medical appliance  
3 further comprise a plurality of flanges that define apertures there  
4 through.

1        61. The medical appliance of claim 58, wherein along the  
2 longitudinal extension of the appliance, the scaffolding forms  
3 triangular patterns.

1        62. The medical appliance of claim 58, wherein the medical  
2 appliance is a stent for installation into the trachea, the scaffolding  
3 forms D shaped lumen to accommodate comfortable tracheal  
4 installation and residence.

1        63. The medical appliance of claim 1, wherein the memory  
2 capable alloy has antimicrobial properties.

1        64. The medical appliance of claim 63, wherein the  
2 antimicrobial alloy is selected from the group consisting of group  
3 eleven metals.

1        65. The medical appliance of claim 1, wherein the  
2 scaffolding further comprising an antimicrobial agent coupled  
3 therewith.

1        66. The medical appliance of claim 65, wherein the  
2 antimicrobial agent is selected from the group consisting of  
3 tetracyclines, rifamycins, macrolides, penicillins, cephalosporins,  $\beta$ -  
4 lactam antibiotics, aminoglycosides, chloramphenicols, sulfonamides,  
5 glycopeptides, quinolones, fusidic acid, trimethoprim, metronidazole,  
6 clindamycin, mupirocin, polyenes, azoles, and beta-lactam inhibitors.

1        67. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises an antiseptic or disinfectant coupled therewith.

1        68. The medical appliance of claim 67, wherein the antiseptic  
2 or disinfectant is selected from the group consisting of thymol,  $\alpha$ -  
3 terpineol, methylisothiazolone, cetylpyridinium, chloroxylenol,  
4 hexachlorophene, cationic biguanides, methylene chloride, iodine  
5 and iodophores, triclosan, furan medical preparations, methenamine,  
6 aldehydes and alcohols.

1        69. The medical appliance of claim 1, wherein the scaffolding  
2 may be made in its entirety or in part of an antimicrobial metal.

3        70. The medical appliance of claim 1, wherein at least one  
4 surface of the scaffolding may have embedded, by ion beam assisted  
5 deposition, therein with atoms of an antimicrobial metal.

1        71. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises a chemotherapeutic agent coupled therewith.

1        72. The medical appliance of claim 71, wherein the  
2 chemotherapeutic agent is selected from the group consisting of  
3 DNA-interactive Agents, Antimetabolites, Tubulin-Interactive Agents,  
4 Hormonal agents and others such as Asparaginase or Hydroxyurea.

1        73. The medical appliance of claim 71, wherein the DNA-  
2 Interactive Agents are selected from the group consisting of  
3 alkylating agents, the DNA strand-breakage agents, the intercalating  
4 topoisomerase II inhibitors, and the nonintercalating topoisomerase II  
5 inhibitors.

1        74. The medical appliance of claim 73, wherein the alkylating  
2 agents are selected from the group consisting of Nitrogen mustards,  
3 aziridines, nitroso ureas, platinum complexes, bioreductive alkylator,  
4 DNA strand breaking agents, Intercalators and nonintercalators.

1        75. The medical appliance of claim 72, wherein the  
2 Antimetabolites are selected from the group consisting of folate  
3 antagonists such as Methotrexate and trimetrexate; pyrimidine  
4 antagonists, such as Fluorouracil, Fluorodeoxyuridine, CB3717,  
5 Azacytidine, Cytarabine; Floxuridine purine antagonists include  
6 Mercaptopurine, 6-Thioguanine, Fludarabine, Pentostatin; sugar  
7 modified analogs include Cytarabine, Fludarabine; and ribonucleotide  
8 reductase inhibitors include Hydroxyurea.

1        76. The medical appliance of claim 1, wherein the scaffolding  
2 further comprises a hormonal agent coupled therewith.

1           77. The medical appliance of claim 76, wherein the hormonal  
2 agent is selected from the group consisting of estrogens, conjugated  
3 estrogens; progestins; and androgens.

4           78. The medical appliance of claim 1, wherein the scaffolding  
5 further comprises an anti-hormonal agent coupled therewith.

1           79. The medical appliance of claim 78, wherein the anti-  
2 hormonal agent is selected from the group consisting of  
3 antiestrogenic, antiandrogen agents, and antiadrenal agents.

1           80. The medical appliance of claim 1, further comprising an  
2 additional distal end wherein the medical appliance forms a  
3 substantially Y-shape.

1           81. The medical appliance of claim 80, wherein along the  
2 longitudinal extension of the appliance, the scaffolding forms  
3 geometrical patterns.

1           82. The medical appliance of claim 81, wherein the  
2 scaffolding further comprises a coating coupled with the scaffolding,  
3 the coating of sufficient thickness to prevent the medical appliance  
4 from becoming epithelialized when installed in the desired portion of  
5 the patient's anatomy.

1           83. The medical appliance of claim 82, wherein the coating  
2 does not inhibit flexing or radial expansion of the medical appliance.

1           84. The medical appliance of claim 83, wherein the coating is  
2 coupled with the medical appliance about the proximal and distal  
3 ends thereof.

1        85. The medical appliance of claim 82, wherein the  
2 dimensions of the scaffolding geometry determine torsionality of the  
3 medical appliance.

1        86. The medical appliance of claim 82, wherein the  
2 scaffolding is formed of a memory capable alloy.

1        87. The medical appliance of claim 86, wherein the  
2 scaffolding is electropolished.

1        88. The medical appliance of claim 82, wherein near the  
2 distal and proximal ends of the scaffolding the medical appliance  
3 further comprise a plurality of flanges that define apertures there  
4 through.

1        89. The medical appliance of claim 81, further comprising a  
2 substantially U-shaped connector member coupled with portions of  
3 the geometrical patterns, the U-shaped connector comprising a  
4 crossing member and a plurality of leg members extending from the  
5 crossing member.

1        90. The medical appliance of claim 89, wherein the  
2 substantially U-shaped connector further comprises a rectangular  
3 detent extending from a leg thereof.

1        90. The medical appliance of claim 89, wherein the length of  
2 the leg members and the degree of the angle at which the legs  
3 extend from the crossing member determines the relative flexibility of  
4 the medical appliance.

1        91. The medical appliance of claim 90, wherein the angle at  
2 which the leg members extend from the crossing member is greater  
3 than 90°.

1        92. The medical appliance of claim 91, wherein the medical  
2 appliance is relatively rigid.

1        93. The medical appliance of claim 91, wherein the angle at  
2 which the leg members extend from the crossing member is 90° or less.

1        94. The medical appliance of claim 92, wherein the medical  
2 appliance is relatively flexible.

1        89. The medical appliance of claim 81, wherein the  
2 geometrical patterns are substantially W-shaped.

1        90. The medical appliance of claim 81, wherein the  
2 geometrical patterns are substantially V-shaped.

1        91. The medical appliance of claim 81, wherein the  
2 geometrical patterns are substantially Z-shaped.

1        92. The medical appliance of claim 81, wherein the  
2 geometrical patterns are substantially S-shaped.

1        93. The medical appliance of claim 81, wherein the  
2 geometrical patterns are substantially X-shaped.

1        94. The medical appliance of claim 80, wherein the medical  
2 appliance is a stent for installation into the trachea of a patient.

1        95. The medical appliance of claim 94, wherein the  
2 scaffolding forms a D shaped lumen to accommodate comfortable  
3 tracheal installation and residence.

1        96. The medical appliance of claim 80, wherein the memory  
2 capable alloy has antimicrobial properties.

1        97. The medical appliance of claim 96, wherein the  
2 antimicrobial alloy is selected from the group consisting of group  
3 eleven metals.

1        98. The medical appliance of claim 80, wherein the  
2 scaffolding further comprising an antimicrobial agent coupled  
3 therewith.

1        99. The medical appliance of claim 98, wherein the  
2 antimicrobial agent is selected from the group consisting of  
3 tetracyclines, rifamycins, macrolides, penicillins, cephalosporins,  $\beta$ -  
4 lactam antibiotics, aminoglycosides, chloramphenicols, sulfonamides,  
5 glycopeptides, quinolones, fusidic acid, trimethoprim, metronidazole,  
6 clindamycin, mupirocin, polyenes, azoles, and beta-lactam inhibitors.

1        100. The medical appliance of claim 80, wherein the  
2 scaffolding further comprises an antiseptic or disinfectant coupled  
3 therewith.

1        101. The medical appliance of claim 100, wherein the  
2 antiseptic or disinfectant is selected from the group consisting of  
3 thymol,  $\alpha$ -terpineol, methylisothiazolone, cetylpyridinium,  
4 chloroxylenol, hexachlorophene, cationic biguanides, methylene

5 chloride, iodine and iodophores, triclosan, furan medical preparations,  
6 methenamine, aldehydes and alcohols.

1 102. The medical appliance of claim 80, wherein the  
2 scaffolding may be made in its entirety or in part of an antimicrobial  
3 metal.

4 103. The medical appliance of claim 80, wherein at least one  
5 surface of the scaffolding may have embedded, by ion beam assisted  
6 deposition, therein with atoms of an antimicrobial metal.

1 104. The medical appliance of claim 80, wherein the  
2 scaffolding further comprises a chemotherapeutic agent coupled  
3 therewith.

1 105. The medical appliance of claim 104, wherein the  
2 chemotherapeutic agent is selected from the group consisting of  
3 DNA-interactive Agents, Antimetabolites, Tubulin-Interactive Agents,  
4 Hormonal agents and others such as Asparaginase or Hydroxyurea.

1 106. The medical appliance of claim 104, wherein the DNA-  
2 Interactive Agents are selected from the group consisting of  
3 alkylating agents, the DNA strand-breakage agents, the intercalating  
4 topoisomerase II inhibitors, and the nonintercalating topoisomerase II  
5 inhibitors.

1 107. The medical appliance of claim 106, wherein the  
2 alkylating agents are selected from the group consisting of Nitrogen  
3 mustards, aziridines, nitroso ureas, platinum complexes, bioreductive  
4 alkylator, DNA strand breaking agents, Intercalators and  
5 nonintercalators.

1        108. The medical appliance of claim 105, wherein the  
2 Antimetabolites are selected from the group consisting of folate  
3 antagonists such as Methotrexate and trimetrexate; pyrimidine  
4 antagonists, such as Fluorouracil, Fluorodeoxyuridine, CB3717,  
5 Azacytidine, Cytarabine; Floxuridine purine antagonists include  
6 Mercaptopurine, 6-Thioguanine, Fludarabine, Pentostatin; sugar  
7 modified analogs include Cyctarabine, Fludarabine; and ribonucleotide  
8 reductase inhibitors include Hydroxyurea.

1        109. The medical appliance of claim 80, wherein the  
2 scaffolding further comprises a hormonal agent coupled therewith.

1        110. The medical appliance of claim 105, wherein the  
2 hormonal agent is selected from the group consisting of estrogens,  
3 conjugated estrogens; progestins; and androgens.

4        111. The medical appliance of claim 80, wherein the  
5 scaffolding further comprises an anti-hormonal agent coupled  
6 therewith.

1        112. The medical appliance of claim 111, wherein the anti-  
2 hormonal agent is selected from the group consisting of  
3 antiestrogenic, antiandrogen agents, and antiadrenal agents.

1        113. The medical appliance of claim 82, wherein the  
2 scaffolding is formed of a memory capable alloy.

1        114. The medical appliance of claim 82, wherein near the  
2 distal and proximal ends of the scaffolding the medical appliance  
3 further comprise a plurality of flanges that define apertures there  
4 through.

1        115. The medical appliance of claim 82, wherein along the  
2 longitudinal extension of the appliance, the scaffolding forms  
3 triangular patterns.

1        116. The medical appliance of claim 82, wherein the medical  
2 appliance is a stent for installation into the trachea of a patient.

1        117. The medical appliance of claim 116, wherein the  
2 scaffolding forms a D shaped lumen to accommodate comfortable  
3 tracheal installation and residence.

1        118. The medical appliance of claim 82, wherein the memory  
2 capable alloy has antimicrobial properties.

1        119. The medical appliance of claim 118, wherein the  
2 antimicrobial alloy is selected from the group consisting of group  
3 eleven metals.

1        120. The medical appliance of claim 82, wherein the  
2 scaffolding further comprising an antimicrobial agent coupled  
3 therewith.

1        121. The medical appliance of claim 120, wherein the  
2 antimicrobial agent is selected from the group consisting of  
3 tetracyclines, rifamycins, macrolides, penicillins, cephalosporins,  $\beta$ -  
4 lactam antibiotics, aminoglycosides, chloramphenicols, sulfonamides,  
5 glycopeptides, quinolones, fusidic acid, trimethoprim, metronidazole,  
6 clindamycin, mupirocin, polyenes, azoles, and beta-lactam inhibitors.

1        122. The medical appliance of claim 82, wherein the  
2 scaffolding further comprises an antiseptic or disinfectant coupled  
3 therewith.

1        123. The medical appliance of claim 122, wherein the  
2        antiseptic or disinfectant is selected from the group consisting of  
3        thymol,  $\alpha$ -terpineol, methylisothiazolone, cetylpyridinium,  
4        chloroxylenol, hexachlorophene, cationic biguanides, methylene  
5        chloride, iodine and iodophores, triclosan, furan medical preparations,  
6        methenamine, aldehydes and alcohols.

1        124. The medical appliance of claim 82, wherein the  
2        scaffolding may be made in its entirety or in part of an antimicrobial  
3        metal.

4        125. The medical appliance of claim 82, wherein at least one  
5        surface of the scaffolding may have embedded, by ion beam assisted  
6        deposition, therein with atoms of an antimicrobial metal.

1        126. The medical appliance of claim 82, wherein the  
2        scaffolding further comprises a chemotherapeutic agent coupled  
3        therewith.

1        127. The medical appliance of claim 126, wherein the  
2        chemotherapeutic agent is selected from the group consisting of  
3        DNA-interactive Agents, Antimetabolites, Tubulin-Interactive Agents,  
4        Hormonal agents and others such as Asparaginase or Hydroxyurea.

1        128. The medical appliance of claim 126, wherein the DNA-  
2        Interactive Agents are selected from the group consisting of  
3        alkylating agents, the DNA strand-breakage agents, the intercalating  
4        topoisomerase II inhibitors, and the nonintercalating topoisomerase II  
5        inhibitors.

1        129. The medical appliance of claim 128, wherein the  
2 alkylating agents are selected from the group consisting of Nitrogen  
3 mustards, aziridines, nitroso ureas, platinum complexes, bioreductive  
4 alkylator, DNA strand breaking agents, Intercalators and  
5 nonintercalators.

1        130. The medical appliance of claim 127, wherein the  
2 Antimetabolites are selected from the group consisting of folate  
3 antagonists such as Methotrexate and trimetrexate; pyrimidine  
4 antagonists, such as Fluorouracil, Fluorodeoxyuridine, CB3717,  
5 Azacytidine, Cytarabine; Floxuridine purine antagonists include  
6 Mercaptopurine, 6-Thioguanine, Fludarabine, Pentostatin; sugar  
7 modified analogs include Cytarabine, Fludarabine; and ribonucleotide  
8 reductase inhibitors include Hydroxyurea.

1        131. The medical appliance of claim 82, wherein the  
2 scaffolding further comprises a hormonal agent coupled therewith.

1        132. The medical appliance of claim 131, wherein the  
2 hormonal agent is selected from the group consisting of estrogens,  
3 conjugated estrogens; progestins; and androgens.

4        133. The medical appliance of claim 82, wherein the  
5 scaffolding further comprises an anti-hormonal agent coupled  
6 therewith.

1        134. The medical appliance of claim 133, wherein the anti-  
2 hormonal agent is selected from the group consisting of  
3 antiestrogenic, antiandrogen agents, and antiadrenal agents.

1        135. The medical appliance of claim 1, wherein the thickness  
2 of the scaffolding is about between 150  $\mu\text{m}$  and 220  $\mu\text{m}$ .

1        136. The medical appliance in accordance with claim 135,  
2 wherein the scaffolding thickness is about between 175  $\mu\text{m}$  and 210  
3  $\mu\text{m}$ .

1        137. The medical appliance of claim 136, wherein the  
2 thickness of the scaffolding is about between 195  $\mu\text{m}$  and 205  $\mu\text{m}$ .

1        138. The medical appliance of claim 137, wherein the  
2 scaffolding thickness is about 205  $\mu\text{m}$ .

3        139. The medical appliance of claim 3, wherein the thickness  
4 of the scaffolding is about between 150  $\mu\text{m}$  and 220  $\mu\text{m}$ .

5        140. The medical appliance in accordance with claim 139,  
6 wherein the scaffolding thickness is about between 175  $\mu\text{m}$  and 210  
7  $\mu\text{m}$ .

1        141. The medical appliance of claim 140, wherein the  
2 thickness of the scaffolding is about between 195  $\mu\text{m}$  and 205  $\mu\text{m}$ .

1        142. The medical appliance of claim 141, wherein the  
2 scaffolding thickness is about 205  $\mu\text{m}$ .

3        143. The medical appliance of claim 82, wherein the thickness  
4 of the scaffolding is about between 150  $\mu\text{m}$  and 220  $\mu\text{m}$ .

5        144. The medical appliance in accordance with claim 143,  
6 wherein the scaffolding thickness is about between 175  $\mu\text{m}$  and 210  
7  $\mu\text{m}$ .

1        145. The medical appliance of claim 144, wherein the  
2 thickness of the scaffolding is about between 195  $\mu\text{m}$  and 205  $\mu\text{m}$ .

1        146. The medical appliance of claim 145, wherein the  
2 scaffolding thickness is about 205  $\mu\text{m}$ .

3        147. The medical appliance of claim 83, wherein the thickness  
4 of the scaffolding is about between 150  $\mu\text{m}$  and 220  $\mu\text{m}$ .

1        148. The medical appliance in accordance with claim 140,  
2 wherein the scaffolding thickness is about between 175  $\mu\text{m}$  and 210  
3  $\mu\text{m}$ .

1        149. The medical appliance of claim 148, wherein the  
2 thickness of the scaffolding is about between 195  $\mu\text{m}$  and 205  $\mu\text{m}$ .

1        150. The medical appliance of claim 149, wherein the  
2 scaffolding thickness is about 205  $\mu\text{m}$ .

1        151. A method of treating a patient suffering from luminal  
2 irregularities, comprising the steps of:

3                providing a medical appliance comprising a scaffolding,  
4 the scaffolding configured to define a substantially cylindrical  
5 member having a distal end and a proximal end and extending  
6 longitudinally there between, forming a lumen there through,  
7 such that when pressure is exerted along varying points of the  
8 longitudinal extension of the appliance, the appliance does not  
9 undesirably foreshorten or elongate;

10                installing the medical appliance in a preferred location of  
11 the anatomy of the patient; and

12                activating the expansion of the medical appliance in the  
13 desired location.

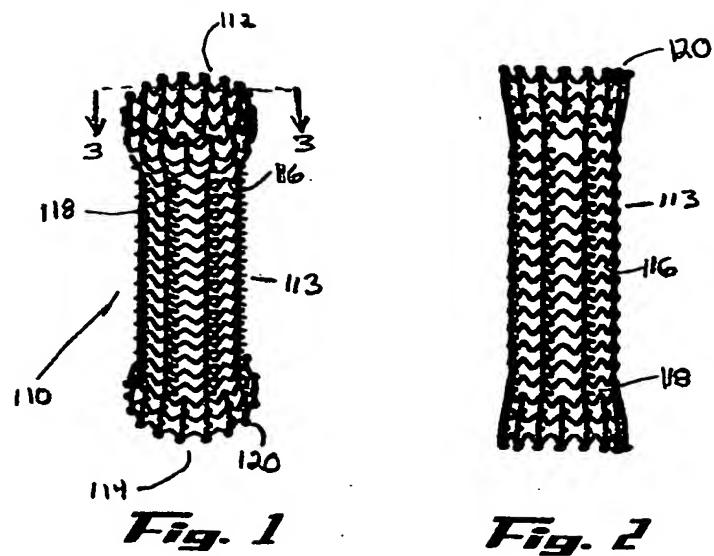
1        152. The method of claim 151, wherein the preferred location  
2 is a non-vascular lumen.

1        153. The method of claim 152, further comprising the step of  
2 removing the medical appliance from the anatomy of the patient.

1        154. The method of claim 152, wherein the medical appliance  
2 further comprises anti-microbial agents coupled therewith.

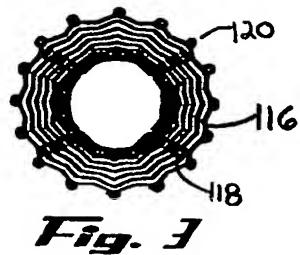
1        155. The method of claim 152, wherein the medical appliance  
2 further comprises chemotherapeutic agents coupled therewith.

1        156. The medical appliance of claim 151, further comprising an  
2 additional distal end wherein the medical appliance forms a  
3 substantially Y-shape.

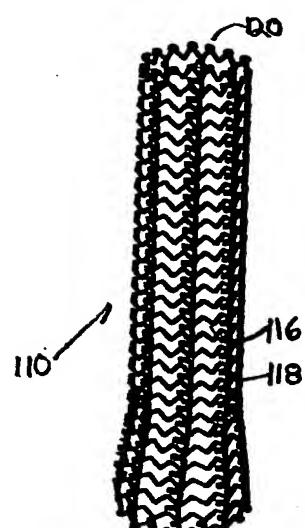


*Fig. 1*

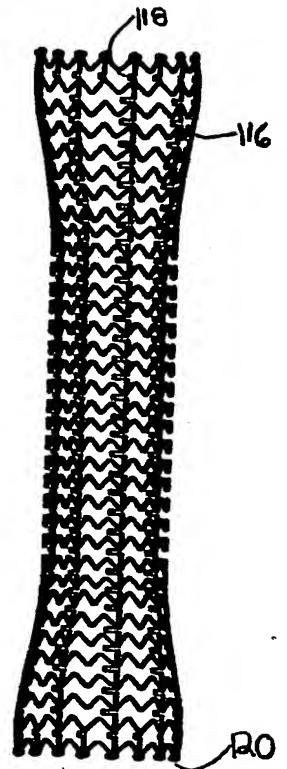
*Fig. 2*



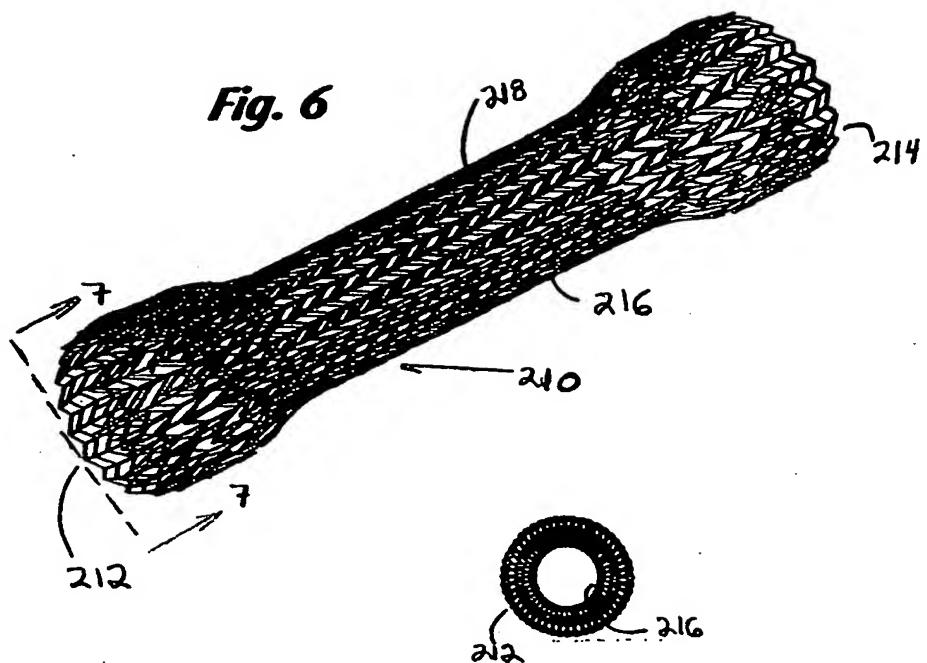
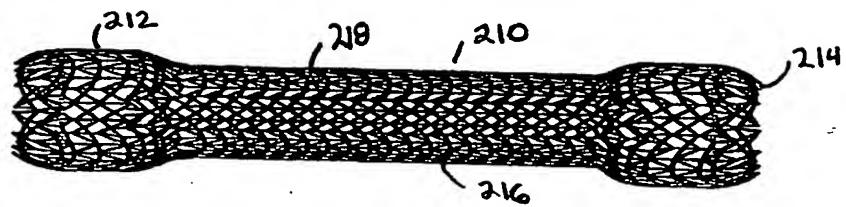
*Fig. 3*

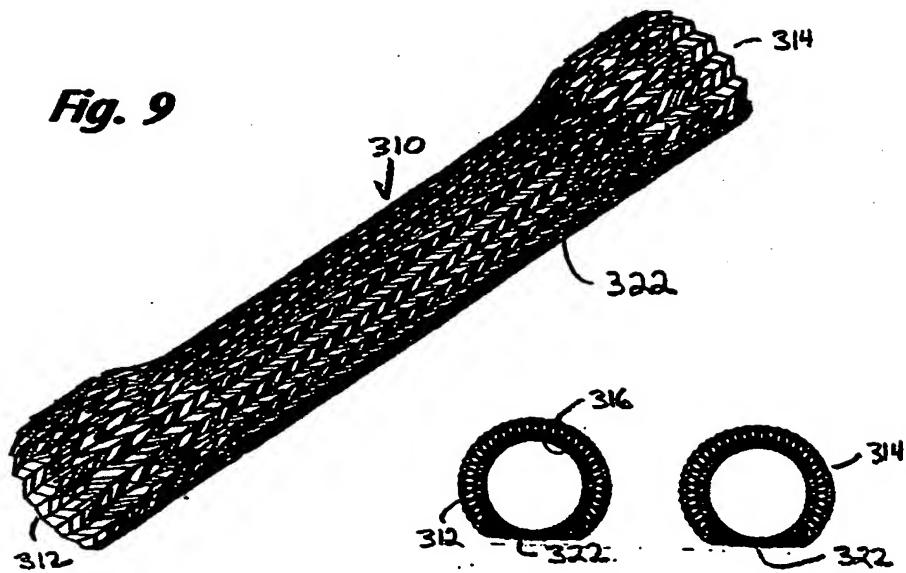
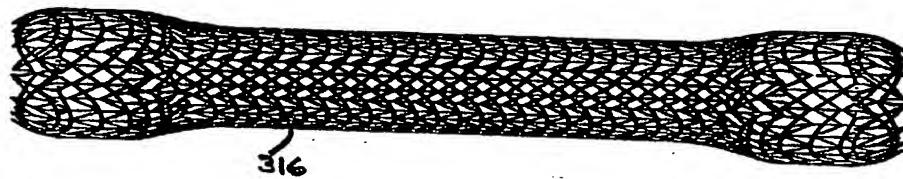
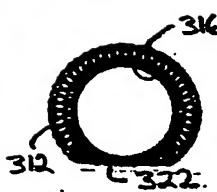
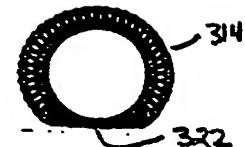
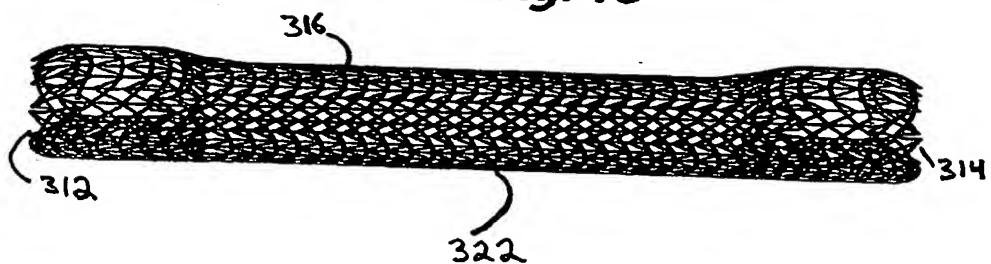


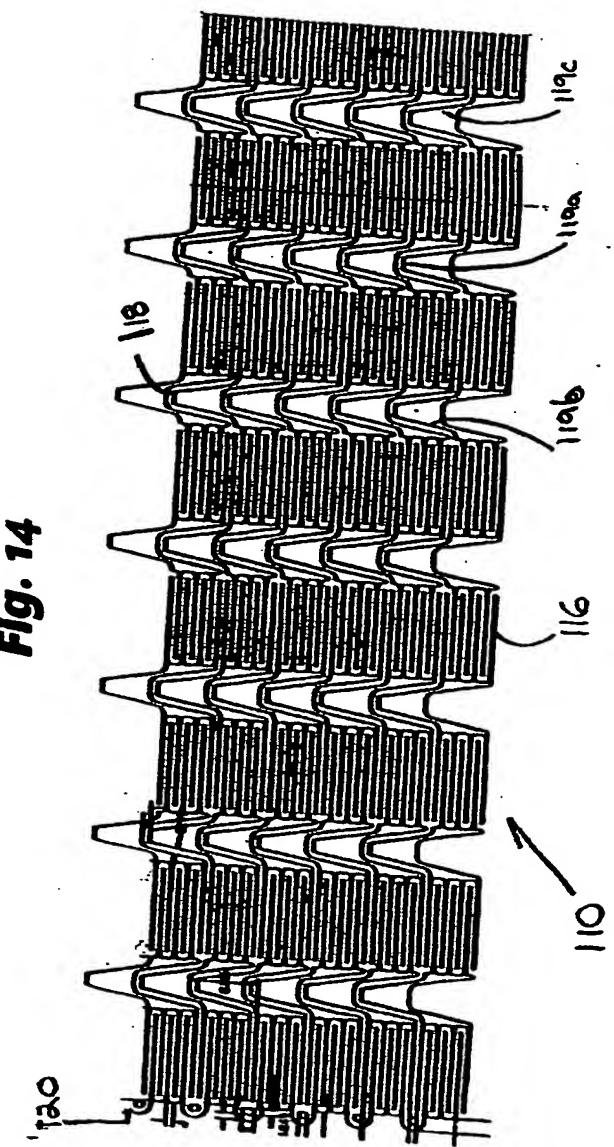
*Fig. 4*



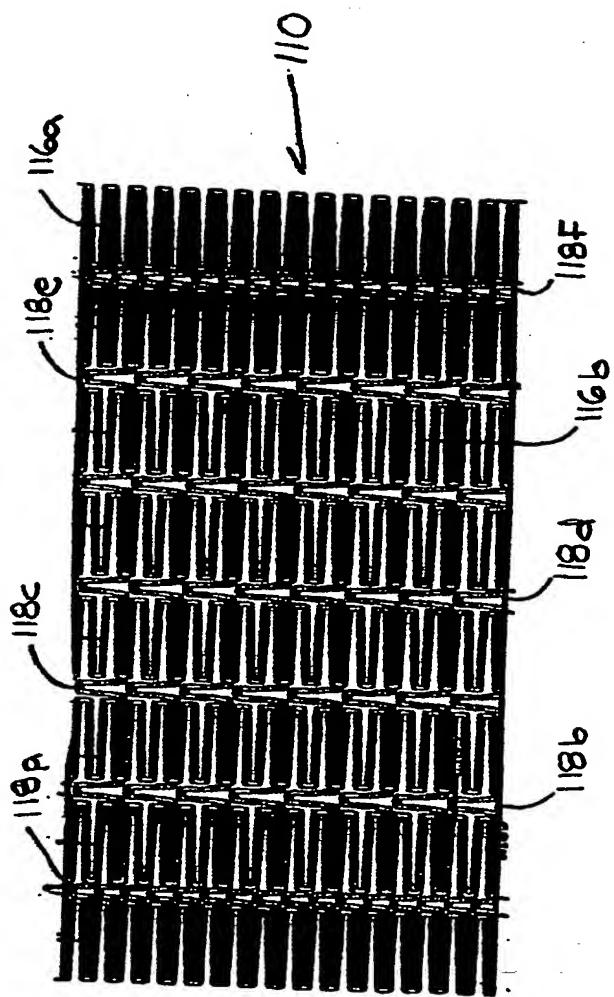
*Fig. 5*

*Fig. 6**Fig. 7**Fig. 8*

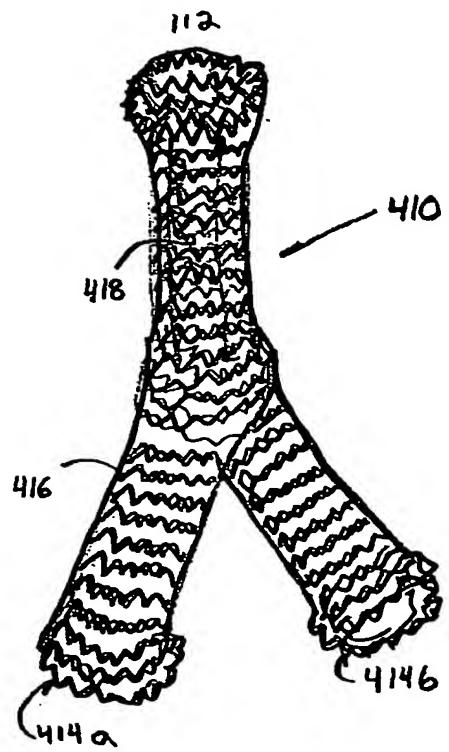
**Fig. 9****Fig. 10****Fig. 11****Fig. 12****Fig. 13**



**Fig. 15**



*Fig. 16*



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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
6 February 2003 (06.02.2003)

PCT

(10) International Publication Number  
WO 03/009773 A3

(51) International Patent Classification<sup>7</sup>: A61F 2/06

LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(21) International Application Number: PCT/US02/22098

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(22) International Filing Date: 5 July 2002 (05.07.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/308,071 26 July 2001 (26.07.2001) US

(71) Applicant: ALVEOLUS INC. [US/US]; 414 West 9th Suite I, Charlotte, NC 28202 (US).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

(72) Inventors: SILVESTRI, Gerard, A.; 602 Chimney Bluff Drive, Mt. Pleasant, SC 29464 (US). FREITAG, Lutz; Theo-Funccius-Strasse 2, 58675 Hemer (DE).

Published:

- with international search report

(74) Agent: ALEXANDER, Tony, D.; Technology Legal Counsel LLC, P.O. Box 1728, Evans, GA 30809 (US).

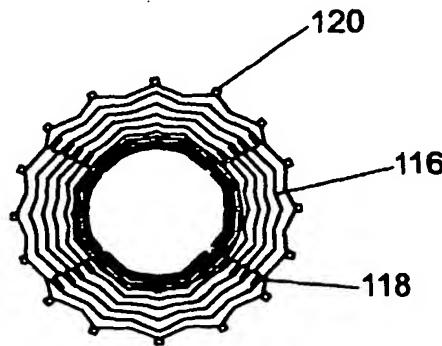
(88) Date of publication of the international search report: 13 November 2003

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,

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WO 03/009773 A3

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/22098

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06  
US CL : 623/1.31, 1.41, 1.46,

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 623/1.31, 1.41, 1.46, 1.15, 1.17, 1.3, 1.32, 1.33, 1.35, 1.43, 1.47, 1.48 and 1.49

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
East text search.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,159,239 A (Greenhalgh) 12 December 2000 (12.12.2000), see entire document.	1, 2, 6, 7, 17-20, 24, 25, 58, 59, 151 and 156
A, P	US 6,409,750 B1 (Hyodoh et al) 25 June 2002 (25.06.2002), see entire document.	1 and 151
A	US 6,136,022 A (Nuñez et al) 24 October 2000 (24.10.2000), see Figs. 1-7.	1, and 151
A	US 6,120,534 A (Ruiz) 19 September 2000 (19.09.2000), see Fig. 5C.	1 and 151
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## CORRECTED VERSION

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
6 February 2003 (06.02.2003)

PCT

(10) International Publication Number  
WO 2003/009773 A3

(51) International Patent Classification<sup>7</sup>: A61F 2/06 SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(21) International Application Number: PCT/US2002/022098 (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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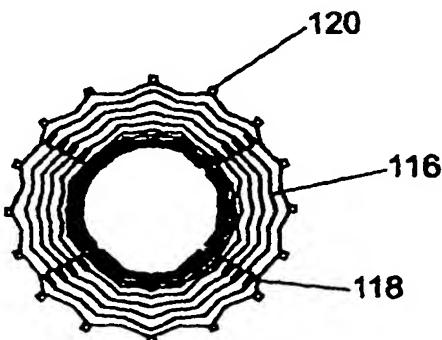
(88) Date of publication of the international search report: 13 November 2003

(48) Date of publication of this corrected version: 6 May 2004

(15) Information about Correction:  
 see PCT Gazette No. 19/2004 of 6 May 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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